

# APHIS Biotechnology: Permitting Progress into Tomorrow

Genetically modified organisms (GMO's) are big news—potatoes that resist attacks by the Colorado potato beetle, papayas that are super resistant to viruses, bananas that might one day carry vaccines to the Third World. Newspapers and magazines regularly announce the latest advancements in the great biotechnology race. While many products are already on the market, many more are being developed and tested every day. The U.S. Department of Agriculture (USDA) is right there to ensure that the GMO's being created today do not pose a risk to other plants and animals tomorrow.

## Genetically Modified Organisms

A GMO is developed by modifying an organism's deoxyribonucleic acid (DNA) for the purpose of creating a better organism. As technology improves, applications for GMO's increase and the number of GMO's being created grows more rapidly. Genetic engineering is being used in the production of pharmaceuticals, nutraceuticals ("functional foods"), gene therapy, and the development of transgenic animals and plants. In 1998, a quarter of the corn, a third of the soybeans, and half of the cotton grown in the United States were GMO's.

Transgenic plants that can tolerate herbicides, resist insects or viruses, or produce modified fruit or flowers are being grown and tested. Copies of genes for these traits have been transferred to the plants by genetic engineering techniques from other unrelated plants, bacteria, or viruses. Corn plants that produce an insecticidal protein to resist European corn borers, the most serious insect threat to American corn today, and potatoes that resist both virus and insect attacks are examples of transgenic plants that have been developed.

## USDA Regulation of Transgenic Plants

The USDA regulates genetically engineered plants through its Animal and Plant Health Inspection Service (APHIS). APHIS administers the Federal Plant Protection Act. This legislation authorizes APHIS to regulate interstate movement, imports to

the United States, and release (for field testing) of "organisms and products altered or produced through genetic engineering, which are plant pests or which there is reason to believe are plant pests." A plant pest is a risk to other plants and ecosystems. The term is generally applied to weeds, insects, diseases, or untested GMO's. Applying the term "plant pest" to a genetically engineered plant means only that the nonpest nature of the plant has yet to be demonstrated. Of the tens of thousands of field tests conducted to date, genetically engineered plants have shown no more pestlike qualities than their nonmodified parents.

APHIS regulations provide a list of the organisms regarded as plant pests so applicants know if the development of their product is subject to APHIS regulations. It does not take an entire organism's DNA to produce a risk, however. Scientists will often use a small section of an organism, such as DNA from a virus, to create a plant resistant to the virus. The new plant would be regarded as a risk until proven otherwise. If an organism is not on the plant-pest list, it still may be subject to APHIS regulations if it is an unclassified organism or there is reason to believe that the resulting GMO is or will be a plant pest. An organism that is subject to APHIS regulation is called a regulated article.

APHIS exercises its regulatory authority through a permit system. A company, academic research institution, or public sector scientist wishing to move or field-test a genetically engineered plant must obtain the necessary permit(s) before proceeding. This permit system is an extension of the longstanding permitting program used for naturally occurring plant pests.

There are three basic types of permits that an applicant developing a genetically engineered plant may be required to obtain. To apply for any of the three permits, an applicant must complete a detailed form (APHIS Form 2000) and send it to the Scientific Services Permit unit of APHIS' Plant Protection and Quarantine (PPQ) program.

If portions of the application contain trade secrets or confidential business information (CBI), the applicant submits two versions of the application, one with CBI marked and included and one with CBI marked and deleted. The CBI-deleted version is the version that is circulated for review by officials outside APHIS, such as State departments of agriculture.

## **Permit for Movement and Importation**

APHIS requires a permit and concurrence of individual State departments of agriculture. To move any genetically engineered organism that is a potential plant pest into the United States or between States, permit applicants must provide APHIS with details about the nature of the organism, its origin, and its intended use.

After the application is reviewed, APHIS makes a preliminary pest risk analysis and sends a letter to the appropriate State department of agriculture asking them to review the proposed movement. APHIS and State officials will inspect the facility that will receive the organism to ensure that the organism will not be accidentally released into the environment. The inspectors will also evaluate facilities, personnel, security, and operational procedures of laboratories, growth chambers, and greenhouses to ensure that National Institutes of Health guidelines for good practices are being followed.

APHIS issues or denies movement permits within 60 days after receiving an application. If granted, the permit is valid for 1 year from the date of issue and must be renewed if additional plant material is moved after that time. If a permit is denied or revoked, the applicant can appeal the decision.

## **Permit for Release Into the Environment**

APHIS also oversees field testing (also called environmental release) of genetically engineered crops. On APHIS Form 2000, an applicant must provide complete information about the plant, including all new genes and new gene products, their origin, the purpose of the test, the experimental design (how the test will be conducted), and precautions to be taken to prevent the escape of pollen, plants, or plant parts from the field test site.

These special precautions routinely include transporting the plants to the field test site in enclosed containers and thoroughly cleaning test plot equipment before and after use. Depending on the plant being field tested, cross pollination is blocked by bagging the flowers, growing crops in cages that keep insects from carrying pollen out, removing the plants' reproductive structures, or isolating the plants from other crops. After harvest, any remaining vegetative material in a field test site is allowed to dry down in the field, followed by cultivation to incorporate remaining plant parts into the soil. The next spring, a field test site typically is treated with herbicide, planted to a different crop, and monitored throughout the growing season. Any unplanned and unwanted plants that sprout are destroyed.

APHIS personnel review the permit application for completeness and assign it to a scientific reviewer who evaluates the proposed field test. APHIS also contacts State agriculture officials where the field test is proposed to get their input.

APHIS prepares an environmental assessment (EA), a document that analyzes any possible environmental impacts the field test could have, as part of the review process. The EA is required by the National Environmental Policy Act, Council on Environmental Quality regulations, and USDA procedures. One permit application can cover field tests in more than one state and field tests do not have size limits. However, APHIS officials take into consideration the scope and size of a field test when they prepare the EA.

APHIS sends written approval or denial of a field test application to the applicant within 120 days. If the field test is approved, APHIS personnel will inspect the field test site near the beginning of the field test, possibly during the test, and after harvest.

Before a genetically engineered crop can be sold commercially, companies must file a petition for USDA exemption. This petition requires more information than a field test permit, including environmental product safety information.

## **Courtesy Permit**

Applicants may request a courtesy permit from APHIS to move or field-test a genetically engineered plant that is not regulated by the agency. Sometimes a nonregulated plant may be similar to one that is regulated by APHIS. Even though it is not required, an APHIS permit may make it easier to move or field-test the plant.

An applicant for a courtesy permit completes certain items on APHIS Form 2000, including a statement of why the applicant believes the plant organism or product should not be subject to APHIS regulation. Within 60 days after the application is received, APHIS will either issue the courtesy permit or advise the applicant that the organism is a regulated article and application for a regular movement or field test permit must be made.

## **Alternatives to the Permit Process**

Obtaining an APHIS permit can be a paper-intensive process that takes time. But it is easier for some crops to move through the permitting process than others. In the spring of 1993, APHIS offered two alternatives to the standard permitting process.

**Notification Process.** APHIS streamlined the permit process for importation, interstate movement, and field testing of six genetically engineered crops: corn, soybeans, cotton, potatoes, tomatoes, and tobacco. Instead of applying for a permit, applicants can notify APHIS that they plan to move or field-test a GMO.

The notification process is a step-by-step procedure designed to protect American agriculture. The planned move or field test of a GMO must meet certain eligibility criteria and performance standards. If it does not, the more involved standard permit process must be followed. If a field test does qualify

for the notification process, APHIS will still require information about the plant, such as the source of any genes used; the method of genetic engineering; and the size, date, and location of the field test. APHIS must receive notification at least 10 days before a GMO's interstate movement and 30 days before field testing or importation into the United States. Detailed annual followup reports are also required.

The notification process was expanded in 1997 to include all genetically engineered plants that meet APHIS selection criteria and performance standards. For example, plants designed to contain or produce pharmaceuticals would not be part of the expanded notification process. If a field test does not meet eligibility and performance standards, the regular field test permit process must be followed.

**Petition Process.** This process allows an applicant to request, in writing, that a regulated plant no longer be regulated. The petition must include scientific details about the genetics of the plant, the nature and origin of the genetic material used, information about indirect effects on other plants, field test reports, and other information required by APHIS, including any information unfavorable to the petition. It is a full disclosure of all that is helpful and harmful about a GMO. To give the public an opportunity to make comments, APHIS publishes all petitions in the Federal Register. The public has 60 days to comment on the petition, and APHIS has up to 180 days to either approve or deny an application once it is deemed complete.

## Additional Information

For more information about the permitting of GMO's, contact:

USDA, APHIS, PPQ  
Scientific Services  
4700 River Road, Unit 136  
Riverdale, MD 20737-1236

or visit the Scientific Services web site at  
<http://www.aphis.usda.gov/ppq/ss/>

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